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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
08/196,154	11/16/1995	PHILIP O. LIVINGSTON	43016-A-PCT-	5954
7590 02/22/2005			EXAMINER	
JOHN P WHITE COOPER AND DUNHAM 1185 AVENUE OF THE AMERICAS NEW YORK, NY 10036			HOLLERAN, ANNE L	
			ART UNIT	PAPER NUMBER
			1642	

DATE MAILED: 02/22/2005

Please find below and/or attached an Office communication concerning this application or proceeding:

Office Action Summary

Application No.

08/196,154

Applicant(s)

LIVINGSTON ET AL.

Examiner

Anne Holleran

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10/21/2005.
- 2a) ☒ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 119,126,127 and 129-142 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 119,126,127 and 129-142 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input checked="" type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. <u>2/16/2005</u> . |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____. | 6) <input type="checkbox"/> Other: _____. |

DETAILED ACTION

1. The amendment filed October 21, 2004 is acknowledged.
2. Claims 119, 126, 127, 129-142 are pending and examined on the merits.
3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections Withdrawn:

4. The rejection of claims 119, 126, 127 and 129-142 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement, is withdrawn in view of the amendment to the claims.
5. The rejection of claims 119, 126, 127 and 129-142 under 35 U.S.C. 112, 2nd paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention, is withdrawn in view of the amendment to the claims and to the specification, and the remarks made on record regarding QS-21.
6. The objection to claims 126 and 129 under 37 CFR 1.75(b), because they appear to claim inventions of the same scope is withdrawn in view of the amendment to claim 126.

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7. The rejection of claims 119, 131, 132 and 134-142 under 35 U.S.C. 103(a) as being unpatentable over Wiegand (U.S. Patent 5,99,914; issued Feb. 4, 1997; filed Nov. 24, 1989) in view of Jennings (U.S. Patent 4,356,170; issued 1982), in view of Neurath (U.S. patent 4,591,552; issued 5/27/1986), in view of Ratcliff (U.S. Patent 5,344,870; issued 9/6/1987), in view of Blincko (U.S. patent 5,256,409; issued 10/26/1993; effective filing 1/25/1991), in view of Marciani, in view of Ritter and further in view of Livingston (Proc. Natl. Acad. Sci. USA 84: 2911-2915, 1987), is withdrawn in view of applicants' persuasive arguments that one of ordinary skill in the art would not have had a reasonable expectation of success in using QS-21 to increase the immunogenicity of a ganglioside conjugate in view of the teachings of Marciani, which are directed to using QS-21 to increase the immunogenicity of a viral peptide antigen.

8. The rejection of claims 132 and 133 under 35 U.S.C. 103(a) as being unpatentable over Wiegand (U.S. Patent 5,99,914; issued Feb. 4, 1997; filed Nov. 24, 1989) in view of Jennings (U.S. Patent 4,356,170; issued 1982), in view of Neurath (U.S. patent 4,591,552; issued 5/27/1986), in view of Ratcliff (U.S. Patent 5,344,870; issued 9/6/1987), in view of Blincko (U.S. patent 5,256,409; issued 10/26/1993; effective filing 1/25/1991), in view of Marciani, in view of Ritter, in view of Livingston (Proc. Natl. Acad. Sci. USA 84: 2911-2915, 1987), and further in view of Irie (U.S. Patent No. 4,557,931), is withdrawn in view of applicants' persuasive arguments that one of ordinary skill in the art would not have had a reasonable expectation of success in using QS-21 to increase the immunogenicity of a ganglioside conjugate in view of the teachings of Marciani, which are directed to using QS-21 to increase the immunogenicity of a viral peptide antigen.

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Rejections Maintained:

9. The provisional rejection of claims 119, 126, 127 and 129-142 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over the pending application No. 08/477,147 is maintained for the reasons of record. Applicants' remarks concerning their intent to file a terminal disclaimer are acknowledged.

New Grounds of Rejection:

10. Claims 119, 126, 127, 129-142 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 119, 129, 131 and 132 are indefinite because they refer to a "GM2:Keyhole Limpet Hemocyanin" molar ratio as a characteristic of the conjugate, when the conjugate comprises a "GM2 derivative" as described in the claims. This rejection would be obviated by amending claims 119, 129, 131 and 132 to recite: "GM2 derivative:Keyhole Limpet Hemocyanin molar ratio..."

Conclusion

No claim is allowed. The claimed inventions are free of the art. Upon receipt of a terminal disclaimer and amendment of claims 119, 129, 131 and 132, as suggested above, the claims will be allowed.

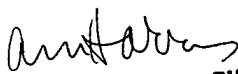
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Any inquiry concerning this communication or earlier communications from the Office should be directed to Anne Holleran, Ph.D. whose telephone number is (571) 272-0833. Examiner Holleran can normally be reached Monday through Friday, 9:30 am to 3:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Siew, can be reached at (571) 272-0787.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist at telephone number (703) 571-1600.

Anne L. Holleran
Patent Examiner
February 16, 2005


ALANA M. HARRIS, PH.D.
PRIMARY EXAMINER